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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/389,082	09/02/99	FITZGERALD	104161

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IM52/1106

EXAMINER
CROSS, L

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

11/6/01

Office Action Summary

Application No.

09/389,082

Applicant(s)

FITZGERALD ET AL.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This Office Action is in response to Applicants' amendment filed on August 23, 2001 and entered as Paper No. 7. Claims 1-13 and 15-19 are pending in the instant application. Claim 14 was cancelled by amendment. Claims 16-19 were newly added.

Withdrawal of Rejections from Previous Office Action

The rejection of claims 3, 12 and 14 under 35 USC 112, second paragraph is withdrawn in view of Applicants' amendments to clarify the claimed invention.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 6, 8-13 and 15-19 remain to be rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,843,767 to Beattie (hereinafter Beattie '767).

Applicants' claimed invention is directed to an assay assembly comprising a chip on which an array of reactive species is immobilized, and storage well having a base and side walls, wherein the storage well contains the chip.

Beattie '767 teaches a micro-fabricated porous apparatus for detecting of binding reactions. The apparatus of Beattie '767 comprises a substrate containing individual regions/sites arrayed across the substrate for binding reactions to take place, and

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biomolecules of predetermined structure which are fixed into each of the individual regions/sites. In Beattie '767 the substrate containing individual regions/sites is a nanoporous glass wafer. Each of the regions/sites is a tapered conical well (storage well) bonded to a face of the glass wafer (col. 5, lines 27-48, lines 53-57). Filled polymers, epoxy resins and related composites are materials used in the arrays. The biomolecules of predetermined structure are disclosed as being binding reagents which are immobilized onto the walls of the wells. The binding reagents are effective for carrying out binding reactions such as those involving small molecules, macromolecules, particles and cellular systems. Regarding the method of manufacturing the assay elements, Beattie '767 teaches at col. 4, lines 40-52 that the recognition elements are attached to the surface of glass or gold films. At col. 13, lines 46-49, the reference teaches that the recognition element (amine containing biopolymer species) is then attached to the walls of the storage well. See also col. 10, example 2; col. 29, line 66 - col. 30, line 43 and figures 1A and 1B.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated within the meaning of 35 USC 102, in view of the teachings of Beattie '767.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 5 and 7 remains to be rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie '767 in view of Great Britain publication 2,147,698 to Albon et al (hereinafter Albon et al '698).

The disclosure of Beattie '767 pertinent to the claimed invention is described in the previous section.

Beattie '767 fails to disclose the use of hot or cold formed projections for retaining the chips in the storage wells. Also, Beattie '767 does not disclose a plurality of carrying trays arranged in a stack.

The use of projections in storage wells for holding assaying items in place is conventional as shown by Albon et al '698. Albon et al '698 teach a test apparatus for immunoassay comprising a holder having a plurality of inserts for reaction wells and a tray having a plurality of reaction wells. The inserts contain specific immunological sensitization. The inserts are removably mountable in the holder via "stud-and-socket" press fitting or screw mounting or by adhesive bonding.

It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to use such projections as disclosed by Albon et al '698 to removably mount the insert insides of the reaction wells.

With respect to the carrying trays being arranged in a stack, this is an obvious manner of carrying several trays which would allow the trays to be packaged easily and also allow easier shipping.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Beattie '767 and Albon et al '698.

Response to Arguments

5. Applicant's arguments filed August 23, 2001 have been fully considered but they are not persuasive. In response to the Beattie '767 reference, Applicants argued that the reference does not teach a chip located within a storage well and does not teach a chip having an array of reactive species located in the storage well. The Examiner disagrees. At col. 1, lines 21-25 and lines 29-32, Beattie '767 discusses the genosensors (miniaturized chips) used in the apparatus. The genosensors contain oligonucleotides fastened to a surface in a two-dimensional array and serve as recognition elements for complimentary sequences present in a target sequence. The recognition elements are reactive species. Beattie '767 further teaches that the recognition elements are immobilized within densely packed pores or channels, arranged in patches across a wafer of solid support material, wherein a storage well is bonded to the wafer.

It is unclear if Applicants are attempting to argue that the genosensors (chips) of Beattie '767 are different from the instant invention because they are immobilized on the walls of the storage well. If Applicants intended this to be their argument, it is not persuasive. Firstly, Beattie teaches that the recognition elements are attached to glass or gold films and further attached to the walls of the storage well. See col. 4, lines 40-

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52 and col. 13, lines 24-49. Secondly, even where Beattie '767 might teach that the recognition elements are immobilized directly onto the walls of the storage well, this teaching would provide for a reactive site portion, which can be construed as a chip, located inside of the storage well.

Therefore, the rejection over Beattie '767 and the rejection over Beattie '767 in view of Albon et al '698 are maintained.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers


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for the organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC

October 31, 2001


Jill Warden
Supervisory Patent Examiner
Technology Center 1700